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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,309	10/26/2001	Rodney A. Welch	096429-9117	2988

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EXAMINER
STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
1652	9

DATE MAILED: 07/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/002,309	WELCH ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Application Status

[1] Claims 1-21 are pending in the application.

[2] Receipt of Information Disclosure Statements (IDSs) filed as Paper Nos. 5 and 8 is acknowledged. The cited references will be considered and a copy of each IDS will be returned in a subsequent Office communication.

Election/Restrictions

[3] Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim(s) 1-11, drawn to an isolated polypeptide, classified in class 435, subclass 220.

II. Claim(s) 12-14, drawn to a genetic construct and a cell comprising said genetic construct, classified in class 435, subclass 325.

III. Claim(s) 15 and 16, drawn to an antibody, classified in class 530, subclass 387.9.

IV. Claim(s) 17, drawn to a method of preventing or treating colitis or hemolytic uremic syndrome by administering an antibody, classified in class 424, subclass 139.1.

V. Claim(s) 18, drawn to a method of preventing colitis or hemolytic uremic syndrome by administering an inactivated polypeptide comprising SEQ ID NO:2, classified in class 514, subclass 2.

VI. Claim(s) 19, drawn to a method of preventing or treating colitis and/or hemolytic uremic syndrome by administering C1 esterase inhibitor, classified in class 514, subclass 2.

VII. Claim(s) 20, drawn to a method for testing a molecule for the ability to reduce proteolysis of C1 esterase inhibitor by an inhibitor protein, classified in class 435, subclass 23.

VIII. Claim(s) 21, drawn to a method for detecting a bacterium comprising a polynucleotide encoding sequence, classified in class 435, subclass 6.

[4] The inventions are distinct, each from the other because:

[5] The genetic construct of Group II, the polypeptide of Group I, and the antibody of Group III each comprises a chemically unrelated structure capable of separate manufacture, use and effect. The genetic construct of Group II has other utility besides encoding polypeptides such as being used as a hybridization probe, the polypeptide of Group I can be made by a method other than expression from the genetic construct such as purification from the natural source or chemical synthesis, and the antibody of Group III can be made by a protein other than a polypeptide expressed from the genetic construct such as a polypeptide produced by purification from the natural source or by chemical synthesis.

[6] The polypeptide of Group I is unrelated to the method(s) of Group(s) IV, VI, and VIII as it is neither used nor made by the method(s) of Group(s) IV, VI, and VIII.

[7] The polypeptide of Group I and the methods of Groups V and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group I can be used as an antigen in the production of the antibody of Group III.

[8] The genetic construct of Group II is unrelated to the method(s) of Group(s) IV-VII as it is neither used nor made by the method(s) of Group(s) IV-VII.

[9] The genetic construct of Group II and the method of Group VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the genetic construct of Group(s) II can be used for expression of the protein of Group I.

[10] The antibody of Group III is unrelated to the method(s) of Group(s) V-VII as it is neither used nor made by the method(s) of Group(s) V-VII.

[11] The antibody of Group III and the method of Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group III can be used as an affinity reagent for the purification of the protein of Group I.

[12] The methods of Groups IV-VIII are independent as they comprise different steps, utilize different products and yield different results.

[13] MPEP § 803 sets forth two criteria for restricting between patentably distinct inventions – 1) the inventions must be independent or distinct and 2) there must be a serious burden on the examiner. MPEP § 803 states, "For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02". Because the inventions of Groups I-VIII are distinct for the reasons given above, have separate classification, and/or each of the inventions requires a separate patent and non-patent literature and/or sequence search, restriction for examination purposes is proper.

[14] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[15] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Thursday from 6:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for this Group is (703) 308-4242. Any inquiry of a general nature or relating to

the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652

07/24/03